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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,674	02/13/2007	Mohammad Djavad Mossalayi	604-790	2319
23117 7590 04/30/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER HUYNH, PHUONG N	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 04/30/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,674	<b>Applicant(s)</b> MOSSALAYI ET AL.	
	<b>Examiner</b> PHUONG HUYNH	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/28/06; 7/13/07.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

Claims 1-57 are pending.

### *Election/Restriction*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Invention I      Claims 1-14, 21, 32, 35-36, 40-41 and 56, drawn to a compound comprising a CD23-binding peptide comprising X<sub>1</sub>, X<sub>2</sub>, X<sub>3</sub>, X<sub>4</sub>, X<sub>5</sub>, X<sub>6</sub>, X<sub>7</sub> and X<sub>8</sub> wherein X<sub>1</sub> is Phe or absent, X<sub>2</sub> is His or Ala, X<sub>3</sub> is Glu, Ser, Ala, Asn, Lys, or Cys, X<sub>4</sub> is Asn, Phe, Gln, Pro, Ser, or Ala, X<sub>5</sub> is Trp, X<sub>6</sub> is Pro, Arg, Glu, Gly, Cys or Lys, X<sub>7</sub> is Ser, Pro, Leu, Thr, Ala, Gly, Asn or absent, and X<sub>8</sub> is Phe, Gly, or is absence, a pharmaceutical composition comprising at least one compound comprising a CD23-binding peptide wherein said peptide comprises X is

Invention II      Claim 15-17, drawn to a method of manufacturing a medicament for the treatment or prophylaxis of a specific disease or disorder comprising incorporation of a specific compound comprising a CD23 binding peptide.

Invention III      Claims 18-20, drawn to a method of treatment or prophylaxis of a specific disease or disorder related to the biological activity of CD23, comprising providing a subject having a specific disease and treating said subject with a specific compound comprising a CD23 binding peptide.

Invention IV      Claims 22-25, 27-28, and 30-31, drawn to an isolated polynucleotide encoding a specific CD23-binding peptide, vector comprising said polynucleotide, and host cell transformed with said recombinant polynucleotide and a pharmaceutical composition comprising said vector.

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Invention V Claim 26, drawn to a transgenic organism comprising a recombinant polynucleotide encoding a specific CD23-binding peptide.

Invention VI Claims 29, 33 and 34, drawn to a diagnostic test in a biological sample for a condition or disease related to the biological activity of CD23 and a method of detecting CD23 using a labeled polypeptide that binds to CD23.

Invention VII. Claims 35, 37-40, 49, 51-52, and 56, drawn to a peptidomimetic of a peptide that binds to CD23 other than SEQ ID NO: 1-10, said peptidomimetic is a retroinverted peptide, a cyclic peptide.

Invention VIII. Claims 42-44 drawn to a method of manufacturing a medicament for the treatment or prophylaxis of a specific disease or disorder comprising incorporation of a specific a peptidomimetic that binds CD23 other than SEQ ID NO: 1-10.

Invention IX. Claims 45-47, drawn to a method of treatment or prophylaxis of a specific disease or disorder related to the biological activity of CD23, comprising providing a subject having a specific disease and treating said subject with a specific peptidomimetic that binds CD23 other than SEQ ID NO: 1-10.

Invention X. Claims 48 and 50, drawn to a diagnostic test in a biological sample for a condition or disease related to the biological activity of CD23 and a method of detecting CD23 using a labeled peptidomimetic that binds CD23 other than SEQ ID NO: 1-10.

Invention XI. Claims 53-55, drawn to an isolated polynucleotide encoding a specific peptidomimetic that binds CD23 other than SEQ ID NO: 1-10, vector comprising said polynucleotide, and host cell transformed with said recombinant polynucleotide and a pharmaceutical composition comprising said vector.

Invention XII. Claim 57, drawn to a method of manufacturing a medicament for the treatment or prophylaxis of a specific disease or disorder comprising incorporation of a specific a peptidomimetic that binds CD23 other than SEQ ID NO: 1-10.

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The inventions listed as Inventions I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among Invention I is a compound comprising a CD23-binding peptide comprising X<sub>1</sub>, X<sub>2</sub>, X<sub>3</sub>, X<sub>4</sub>, X<sub>5</sub>, X<sub>6</sub>, X<sub>7</sub> and X<sub>8</sub> wherein X<sub>1</sub> is Phe, X<sub>2</sub> is His, X<sub>3</sub> is Glu, X<sub>4</sub> is Asn, X<sub>5</sub> is Trp, X<sub>6</sub> is Pro, X<sub>7</sub> is Ser and X<sub>8</sub> is absence. However, the German patent DE19749277A1 (or record, PTO 1449) teaches such compound. The patent teaches a compound having an identical amino acid sequence X<sub>1</sub> is Phe, X<sub>2</sub> is His, X<sub>3</sub> is Glu, X<sub>4</sub> is Asn, X<sub>5</sub> is Trp, X<sub>6</sub> is Pro, X<sub>7</sub> is Ser and X<sub>8</sub> is absence. The reference peptide is fused to albumin, see abstract, in particular. Given the claimed compound has identical amino acid, whatever property that applicants claimed, i.e. binds CD23 is necessary presence.

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions I-VI are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Accordingly, Groups I-XII are not so linked as to form a single general inventive concept and restriction is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Due to the complexity of the claimed invention an oral restriction was not made.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all claims to the elected product claim are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B O'Hara can be reached on (571) 272-0878. The IFW official Fax number is (571) 273-8300.

Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Phuong Huynh/

Primary Examiner, Art Unit 1644

April 25, 2008